UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF TEXAS

DAVID WILLIAMS AND DARRELL MULVANEY ***Plaintiffs,*** v. PFIZER, INC., AND PHARMACIA & UPJOHN, CO. and WATSON PHARMACEUTICALS, INC. ***Defendants.***	§ § § § § § § § § § §	COMPLAINT AND DEMAND FOR JURY Civil Action No.: 4:14-cv-02285

PLAINTIFFS' ORIGINAL COMPLAINT AND DEMAND FOR JURY

Plaintiffs, DAVID WILLIAMS and DARRELL MULVANEY, by and through undersigned counsel, by way of complaint against Pfizer, Inc., and Pharmacia & Upjohn Co. (hereinafter "Depo-Testosterone Defendants" or collectively "Pfizer") and Watson Pharmaceuticals, Inc. (hereinafter "Depo-Testosterone Defendants" or "Watson") and allege as follows upon information and belief:

INTRODUCTION

1. This case involves the prescription drug Depo Testosterone, which is manufactured, sold, distributed, marketed and promoted by Defendants as a testosterone replacement therapy.

2. Defendants, respectively, misrepresented that Depo Testosterone is safe and effective treatment for hypogonadism or "low testosterone, when in fact the drug causes serious medical problems, including life-threatening cardiac events, strokes, and thrombolytic events.

3. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of Testosterone Replacement Therapy products collectively engaged in aggressive direct-to-consumer and physician promotion, marketing and advertising to created and expand a market for Testosterone Replacement Therapy including Defendants Depo Testosterone products and further engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "Low T".

4. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, individuals diagnosed with Low T has increased exponentially. This has directly related to Depo Testosterone's sales increasing to over several hundred millions dollars.

5. However, consumers of Depo Testosterone were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

PARTIES

6. Plaintiff DAVID ALLEN WILLIAMS is a competent adult and resident of Chehalis, Washington.

7. Plaintiff DARRELL MULVANEY is a competent adult and resident of Goffstown, New Hampshire.

8. Defendant Pfizer, Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of New York and maintains its principal place of business at 235 East 42nd Street, New York, NY 10017 and at all times relevant to this cause of action was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling,

promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Texas, New Hampshire, and Washington. Defendant Pfizer, Inc. may be served at 235 East 42nd Street, New York, NY 10017.

9. Defendant Pharmacia & Upjohn Co. ("Pharmacia") is a corporation organized and existing under the laws of the state of New York and maintains its principal place of business at 235 East 42nd Street, New York NY 10017 and at all times relevant to this cause of action, was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Texas, New Hampshire, and Washington. Defendant Pharmacia & Upjohn Co. may be served at 235 East 42nd Street, New York, NY 10017.

10. Defendant Watson Pharmaceuticals, Inc., ("Watson") is a corporation organized and existing under the laws of the State of New Jersey and maintains a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054 and at all times relevant to this cause of action was engaged in the business of designing, testing, studying, researching, evaluating, endorsing, formulating, compounding, manufacturing, producing processing, assembling, inspecting distributing marketing, labeling, promoting, advertising, packaging, selling, prescribing, or otherwise placing Depo Testosterone in the stream of interstate commerce of the United States, including Texas, New Hampshire, and Washington. Defendant Watson Pharmaceuticals, Inc. may be served at Legal Department, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NY 07054.

JURISDICTION AND VENUE

11. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy as to each plaintiff exceeds $75,000.00, exclusive of interest and costs.

12. Venue in this District is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district.

GENERAL ALLEGATIONS

13. This action is for damages brought by Plaintiffs, DAVID ALLEN WILLIAMS and DARRELL MULVANEY.

14. Plaintiffs were prescribed and supplied with, received, taken and applied the prescription drug Depo Testosterone, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiffs to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

15. Defendants' wrongful acts, omission, and fraudulent misrepresentation caused and/or were substantial factors in Plaintiffs' injuries and damages.

16. At all times herein mentioned, the Depo Testosterone Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Depo Testosterone for the use by Plaintiffs.

17. At all times herein mentioned, Defendants were authorized to do business within the state of residence of Plaintiffs.

18. At all times herein mentioned, the officers and directors of Defendants participated in authorized, and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs.

19. Plaintiff WILLIAMS used the Defendants' product Depo Testosterone during the time period between 2002 to present. During this time period of usage, WILLIAMS suffered multiple significant adverse health events, including but not limited to, a heart attack on or about August 11, 2011.

20. Plaintiff WILLIAMS files this lawsuit within the applicable limitations period of experiencing his injury and first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when WILLIAMS's injuries were discovered their cause was unknown to him. Plaintiff WILLIAMS did not suspect, nor did he have reason to suspect, that he had been injured, the cause of injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, WILLIAMS was prevented from discovering this information sooner because Defendants' herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug Depo Testosterone are safe and free from serious side effects, and Defendants have

fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

21. Plaintiff MULVANEY used the Defendants' product Depo Testosterone during the time period between 2010 to present. During this time period of usage, MULVANEY suffered multiple significant adverse health events, including but not limited to, pulmonary emboli on or about August 10, 2011.

22. Plaintiff MULVANEY files this lawsuit within the applicable limitations period of experiencing his injury and first suspecting that said drug caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when MULVANEY's injuries were discovered their cause was unknown to him. Plaintiff MULVANEY did not suspect, nor did he have reason to suspect, that he had been injured, the cause of injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, MULVANEY was prevented from discovering this information sooner because Defendants' herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug Depo Testosterone are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

OVERVIEW

23. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or non-production of testosterone.

24. In 1999, it was estimated that hypogonadism was estimated to affect approximately "one million American men."

25. In 2000, pharmaceutical companies involved in testosterone replacement therapy estimated that the market was "four to five million American men." By 2003, the number increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled, "Trends in Androgen Prescribing in the United States, 2001 – 2011" indicated that many men who get testosterone prescription have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigues, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

26. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively coordinated a massive marketing, promotional and advertising campaign designed to convince men that they suffer from low testosterone. Defendants and the other companies orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to users, and online media.

27. The coordinated marketing, promotion and advertising suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of these "symptoms." These "symptoms" include listlessness, increased body fat, and moodiness—all

general symptoms that is often a result of aging, weight gain, or lifestyle, rather than low testosterone.

28. Since the FDA approved Depo Testosterone, Defendants and other unnamed pharmaceutical corporations have also sought to convince primary care physicians that low testosterone levels is widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

29. Defendants successfully created a robust and previously non-existent market for their drug. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively spent millions if not $100 million in promoting testosterone replacement therapy and to convince millions of men to discuss testosterone placement with their doctors, and consumers and physicians relied on Defendants' promises of safety and ease.

30. Millions was also spent by Defendants and other unnamed pharmaceutical corporations on the unbranded marketing, advertising and promotion. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively had sales over $2 Billion in 2013. Sale of replacement therapies has doubled more than since 2006, and is expected to triple to $5 Billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, "Is Testosterone Drugs the Next Viagra?", May 10, 2012, Bloomberg Businessweek, available at: http://www.businessweek.com/articles2012-05-10/is-testosteronerugs-the-next-viagra.

31. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of testosterone replacement products like Depo Testosterone is safe for human use, even

though Defendants knew these statements to be false, and even though Defendants had no reasonable grounds to believe them to be true.

32. There have been a number of studies concluding that testosterone therapy causes a sudden increase in hematocrit, hemoglobin and estradiol, and associating its use with increased the risk of heart attacks and strokes and blood clots. Defendants knew or in the exercise of reasonable care should have known that their product Depo Testosterone was defectively designed, unreasonable dangerous in normal use, and highly likely to cause injury or death, but it failed to provide adequate warnings about these known risks.

FACTUAL ALLEGATIONS

33. The Food and Drug Administration approved Depo Testosterone in July, 1979.

34. Depo Testosterone is an intramuscular injection, containing testosterone cypionate which is the oil-soluble 17 (beta)-cyclopentylpropionate ester of the androgenic hormone testosterone.

35. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

36. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

37. In men, testosterone levels normally begin a gradual decline after the age of thirty.

38. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

39. Testosterone may produce undesirable side-effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism and death.

40. In some patient populations, Depo Testosterone use may increase the incidence of myocardial infarctions and death by over 500%.

41. Defendants' marketing strategy along with that of and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew, or should have known, would result from use of its products.

42. Defendants successfully marketed their respective product Depo Testosterone by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent amount U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy was actually attributable to "Low-T."

43. Defendants' and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively engaged in an advertising program that sought to create the image and belief by consumers and their physicians that the use of Depo Testosterone and other testosterone replacement products was safe methods of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false. The Defendants had no reasonable grounds to believe them to be true.

44. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Depo Testosterone. Defendants and other unnamed pharmaceutical corporations involved in the manufacture, sale, distribution, marketing and promotion of testosterone replacement therapy products collectively deceived potential Depo Testosterone users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

45. Defendants concealed material relevant information from potential Depo Testosterone users and minimized user and prescriber concern regarding the safety of Depo Testosterone.

46. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that Defendants adequately tested Depo Testosterone for all likely side effects.

47. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Depo Testosterone. If Plaintiff had known the risks and dangers associated with Depo Testosterone, Plaintiff would not have used Depo Testosterone and consequently would not have been subject to its serious side-effects.

SPECIFIC FACTUAL ALLEGATIONS

48. Plaintiff DAVID ALLEN WILLIAMS was 49 years of age, in 2002, when he was prescribed testosterone replacement therapy for symptoms he attributed to low testosterone after viewing Defendants' advertisements.

49. Plaintiff WILLIAMS was prescribed and took injections of Depo Testosterone between 2002 to present.

50. The Depo Testosterone injections caused physical and emotional impairment which affected his life. These impairments included, but were not limited to a heart attack on or about August 11, 2011.

51. Prior to using Depo Testosterone Williams had no history of cardiac events.

52. Plaintiff DARRELL MULVANEY was 58 years of age, in 2010, when he was prescribed testosterone replacement therapy for symptoms he attributed to low testosterone after viewing Defendants' advertisements.

53. Plaintiff MULVANEY was prescribed and took injections of Depo Testosterone between 2010 to present.

54. The Depo Testosterone injections caused physical and emotional impairment which affected his life. These impairments included, but were not limited to suffering from pulmonary emboli on or about August 10, 2011.

55. Prior to using Depo Testosterone MULVANEY had no history of thrombotic events.

56. Plaintiffs have and will sustain significant general and special damages, including medical expenses, lost wages, diminished economic horizons, and other items of recoverable damages for which they seek maximum recovery as a matter of law.

57. Had Defendants properly disclosed the risks associated with the use of their product Depo Testosterone, Plaintiffs would have avoided the risk of injury either not using testosterone replacement therapy at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting their health.

FEDERAL REQUIREMENTS

58. Defendants had the obligation to comply with the law in the manufacture, design, and sale of their product Depo Testosterone.

59. Upon information and belief, Defendants, each individually, in solido, and/or jointly, violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

60. Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of their product, AndroGel, including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations.

CAUSES OF ACTION

Count I – Strict Liability – Failure to Warn

61. Plaintiffs hereby incorporate each and every allegation set forth above in the paragraphs of this Complaint as if fully rewritten herein.

62. The Defendants are liable under the theory of product liability as set forth in §§402A and 402B of the Restatement of Torts 2d.

63. The Depo Testosterone manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers, including venous thrombosis, and their health care providers of such risks.

64. Defendants failed to adequately warn consumers, including PLAINTIFFS, and their health care providers that Depo Testosterone could cause increased hematocrit levels and other

physiological adverse health events that could cause heart attacks, strokes, pulmonary embolisms, cardiovascular events, blood clots, and death.

65. Defendants failed to adequately warn consumers, including PLAINTIFFS, and their health care providers that while a patient was taking Depo Testosterone it was necessary to frequently monitor hematocrit levels and perform other pertinent medical tests to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events, blood clots, and death.

66. The Depo Testosterone manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Depo Testosterone, Defendants failed to provide an adequate warning to consumers, including PLAINTIFFS, and their health care providers, despite knowledge that the product could cause serious injury.

67. As a direct and proximate result of PLAINTIFFS' reasonably anticipated use of Depo Testosterone as manufactured, designed, sold, supplied, marketed, and introduced into the stream of commerce by Defendants, PLAINTIFFS suffered and continues to suffer from the injuries and damages set forth in this Complaint.

Count II – Strict Liability – Design Defect

68. Plaintiffs hereby incorporate each and every allegation set forth above in the paragraphs of this Complaint as if fully rewritten herein.

69. The Defendants are liable under the theory of product liability as set forth in §§402A and 402B of the Restatement of Torts 2d.

70. Defendants and/or their corporate predecessors are the manufacturers, designers, distributors, sellers, labelers, or suppliers of Depo Testosterone.

71. The Depo Testosterone manufactured and supplied by the Defendants and/or their corporate predecessors was defective in design or formulation in that, when it left the hands of the Defendants and/or their corporate predecessors, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

72. The foreseeable risks associated with the design or formulation of Depo Testosterone include, but are not limited to, the fact that its design or formulation is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

73. As a direct and proximate result of PLAINTIFFS using Depo Testosterone as manufactured, designed, sold, labeled, supplied, marketed and introduced into the stream of commerce by the Defendants and/or their corporate predecessors, as well as Defendants' and/or their corporate predecessor's failure to comply with federal standards, he has suffered and continues to suffer from the injuries and damages set forth in this Complaint.

Count III – Negligence

74. Plaintiffs hereby incorporate each and every allegation set forth above in the paragraphs of this Complaint as if fully rewritten herein.

75. At all times relevant hereto, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe, and adequately warn of the risks and dangers of Depo Testosterone.

76. At all times relevant hereto, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected,

marketed, labeled, packaged, prepared for use, and sold Depo Testosterone and failed to adequately test and warn of the risks and dangers of Depo Testosterone.

77. Despite the fact that Defendants knew or should have known that Depo Testosterone caused unreasonable, dangerous side effects, Defendants continued to market Depo Testosterone to consumers including PLAINTIFFS, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, erectile dysfunction, depression, loss of muscle mass, and other conditions that Depo Testosterone marketing materials claim are caused by "Low T."

78. Defendants knew or should have known that consumers such as PLAINTIFFS would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

79. As a direct and proximate result of the negligence of Defendants, PLAINTIFFS suffered and continues to suffer from the injuries and damages set forth in this Complaint.

Count IV – Breach of Implied Warranty

80. Plaintiffs hereby incorporate each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten.

81. At all times relevant hereto, Defendants impliedly warranted to PLAINTIFFS and their agents and physicians that Depo Testosterone was of merchantable quality and safe and fit for the use for which it was intended.

82. At all times relevant hereto, PLAINTIFFS were unskilled in the research, design, and manufacture of medical drugs, including Depo Testosterone, and reasonably relied on the skill, judgment, and implied warranty of the Defendants in using Depo Testosterone.

83. Depo Testosterone was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Depo Testosterone has dangerous propensities when used as intended and will cause severe injuries to users.

84. As a direct and proximate result of Defendants' breach of implied warranties, PLAINTIFFS suffered and continue to suffer from the injuries and damages set forth in this Complaint.

Count V – Breach of Express Warranty

85. Plaintiffs hereby incorporates by reference each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten herein.

86. At all times relevant hereto, Defendants expressly represented and warranted to PLAINTIFFS and his agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the general public, that Depo Testosterone is safe, effective, fit and proper for its intended use. Plaintiffs purchased Depo Testosterone in reliance upon these express warranties.

87. In using Depo Testosterone, PLAINTIFFS relied on the skill, judgment, representations, and aforementioned express warranties of Defendants. These warranties and representations were false in that Depo Testosterone is unsafe and unfit for its intended uses.

88. As a direct and proximate result of Defendants' breach of express warranties, PLAINTIFFS suffered and continues to suffer from the injuries and damages set forth in this Complaint.

Count VI – Fraud

89. Plaintiffs hereby incorporate by reference each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten herein.

90. At all times relevant hereto, Defendants willfully deceived PLAINTIFFS by concealing from them, their physicians, and the general public, the true facts concerning Depo Testosterone, which the Defendants had a duty to disclose.

91. At all times relevant hereto, Defendants conducted a sales and marketing campaign to promote the sale of Depo Testosterone and willfully deceived PLAINTIFFS, their physicians, and the general public as to the benefits, health risks, and consequences of using Depo Testosterone. Defendants knew of the foregoing, that Depo Testosterone is not safe, fit, or effective for human consumption, that using Depo Testosterone is hazardous to health, and that Depo Testosterone has a propensity to cause serious injuries to its users, including but not limited to those injuries suffered by Plaintiffs.

92. Defendants concealed and suppressed the true facts concerning Depo Testosterone with the intent to defraud PLAINTIFFS, in that Defendants knew that Plaintiffs' physicians would not prescribe Depo Testosterone and Plaintiffs would not have used Depo Testosterone if they were aware of the true facts concerning its dangers.

93. As a direct and proximate result of Defendants' fraudulent and deceitful conduct, PLAINTIFFS suffered and continue to suffer from the injuries and damages set forth in this Complaint.

Count VII – Negligent Misrepresentation

94. Plaintiffs hereby incorporate each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten herein.

95. At all times relevant hereto, Defendants made misrepresentations to PLAINTIFFS, their physicians, and the general public, including but not limited to the misrepresentation that Depo Testosterone was safe, fit and effective for human consumption. At all times relevant hereto, Defendants conducted a sales and marketing campaign to promote the sale of Depo Testosterone and willfully deceived Plaintiffs, their physicians, and the general public as to the health risks and consequences of the use of Depo Testosterone.

96. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, sales representatives, and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients, and the public, with the intention of inducing reliance and the prescription, purchase, and use of the subject product.

97. The abovementioned representations made by Defendants were in fact false, in that Depo Testosterone is not safe, fit, and effective for human consumption; using Depo Testosterone is hazardous to health; and Depo Testosterone has a propensity to cause serious injuries, including those injuries suffered by PLAINTIFFS.

98. The abovementioned representations made by Defendants were each made with the intention of inducing reliance and the prescription, purchase, and use of Depo Testosterone.

99. In reliance upon Defendants' misrepresentations, and each of them, PLAINTIFFS were induced to purchase and use Depo Testosterone. If Plaintiffs had known of the true facts concealed by the Defendants, they would not have used Depo Testosterone. The reliance of Plaintiffs upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

100. As a direct and proximate result of the foregoing negligent misrepresentations made by Defendants, PLAINTIFFS suffered and continue to suffer from the injuries and damages set forth in this Complaint.

Count VIII – Negligence Per Se

101. Plaintiff hereby incorporates each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten herein.

102. At all times relevant hereto, Defendants owed PLAINTIFFS a duty of care imposed by law pursuant to C.F.R. 201.57 to warn of serious adverse reactions and potential safety hazards in the labeling of Depo Testosterone.

103. At all times relevant hereto, Defendants' labeling for Depo Testosterone did not adequately warn of the serious side effects associated with Depo Testosterone, including the development of cardiac injuries, thrombotic events, and possibly death, thereby breaching Defendants' duty of care pursuant to C.F.R. 201.57.

104. As a further part of their duty to exercise reasonable care, at all times relevant hereto, Defendants were obligated to follow public laws and regulations enacted and promulgated to protect the safety of persons such as PLAINTIFFS, including 21 U.S.C. §§ 331(a) & 352, and other statutes and regulations, which make it unlawful to misbrand prescription drug products.

105. At all times relevant hereto, the labeling, including package inserts, for Depo Testosterone failed to conform to the requirements of 21 U.S.C. § 352, and therefore violated 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

106. Defendants misbranded Depo Testosterone and thus violated 21 U.S.C. § 352 because Depo Testosterone is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

107. Because the Defendants each had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand Depo Testosterone, and because each of them violated this duty, they are guilty of negligence per se.

108. Depo Testosterone is further misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

109. Defendants also violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Depo Testosterone.

110. Depo Testosterone is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

111. Depo Testosterone is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., cardiac arrest).

112. Defendants have violated 21 C.F.R. § 210.122 because Depo Testosterone's labeling and packaging materials do not meet the appropriate specifications.

113. Defendants have violated 21 C.F.R. § 310.303 in that Depo Testosterone is not safe and effective for its intended use.

114. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to report adverse events associated with Depo Testosterone as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

115. Defendants violated 21 C.F.R. §§ 310.305 & 314.80 by failing to conduct an investigation of each adverse event associated with Depo Testosterone, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

116. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Depo Testosterone or otherwise received by Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

117. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as PLAINTIFFS, making Defendants liable to Plaintiff, and further, because each of them violated the above referenced duties required by these statutes and regulations, they are guilty of negligence per se.

118. As a direct and proximate result of Defendants' negligence per se, PLAINTIFFS suffered and continues to suffer from the injuries and damages set forth in this Complaint.

Count IX – Fraudulent Misrepresentation

119. Plaintiffs repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

120. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that Depo Testosterone, had been tested and found to be safe and effective for its intended use as testosterone replacement therapy.

121. The representations made by Defendants were, in fact, false.

122. Defendants failed to exercise ordinary care in the representation of Depo Testosterone, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Depo Testosterone's high risk of unreasonable, dangerous side effects.

123. Defendants breached their duty in representing Depo Testosterone's serious side effects to the medical and healthcare community, to the Plaintiffs, the FDA and/or the public in general.

124. By reason of the foregoing Plaintiffs have experienced and/or are at risk of experiencing serious and dangerous side effects including but not limited to, heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including monitoring and/or medications, and fear of developing any of the above named health consequences.

125. As a result of the foregoing acts and omissions the Plaintiffs require and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical and/or hospital care, attention, and services.

Count X – Punitive Damages

126. Plaintiff hereby incorporates each and every allegation as set forth above in the paragraphs of this Complaint as if fully rewritten herein.

127. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and malicious. Defendants committed these acts with fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequence, and with a conscious disregard for the rights and safety of PLAINTIFFS and other Depo Testosterone users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Depo Testosterone. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

128. At all times relevant hereto, Defendants knew or should have known that Depo Testosterone was in a defective condition and that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants knew or should have known that Depo Testosterone presented a substantial and unreasonable risk of harm to the public, and as such, Defendants unreasonably subjected consumers of said drugs, including PLAINTIFFS, to risk of injury or death from using Depo Testosterone.

129. Despite its knowledge, Defendants, acting through its officers, directors, and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Depo Testosterone and failed to warn the public, including

PLAINTIFFS, as to the extreme risk of injury occasioned by said defects inherent in Depo Testosterone. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Depo Testosterone despite knowing these actions would expose persons to serious danger, in order to advance Defendants' pecuniary interest and monetary profits.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiffs:

A. General damages in an amount that will conform to proof at time of trial;

B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Loss of earnings and impaired earning capacity according to proof at the time of trial;

D. Medical expenses, past and future, according to proof at the time of trial;

E. For past and future mental and emotional distress, according to proof;

F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Dated: August 8, 2014

Respectfully submitted,

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